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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,720	08/25/2003	Christine Markert-Hahn	810102.401	3616

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

MAIL DATE DELIVERY MODE

11/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/647,720	<b>Applicant(s)</b> MARKERT-HAHN ET AL.	
	<b>Examiner</b> Joyce Tung	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The applicant's response filed 4/03/07 to the Office action has been entered. Claims 1-11 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/03/07 has been entered.

Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herman et al. (5,786,146, issued July 28, 1998) in view of Gagna (2003/0096273, issued May 22, 2003).

Herman et al. disclose a methylation specific PCR (See the Abstract). The method involves the step of conversion<sup>of</sup> cytosine to uracil. Bisulfite modification includes incubating the nucleic acid in the presence of sulfite ions, binding the deaminated nucleic acid to a solid phase. Modified DNA was purified. Modification was completed by NaOH treatment, followed by ethanol precipitation (See column 11, lines 16-28).

Herman et al. do not disclose directly binding a nucleic acid to a solid phase.

Gagna discloses a method for the immobilization of a nucleic acid molecule on a solid phase (See pg. 1 [0008]). Once so immobilized, the molecules can be used in various assays (See pg. [0002]). The immobilization procedure of nucleic acid is without any compound mediation (See pg. 11, [0140]-[0145]). The solid support can be glass (see pg. 12, [0163]).

One of ordinary skill in the art would have been motivated to apply the method of Gagna for the immobilization of nucleic acid without any compound mediation because as indicated by Gagna, once so immobilized, the molecules can be used in various assays (See pg. [0002]). It would have been prima facie obvious to immobilize a nucleic acid for conversion of cytosine bases to uracil bases.

None of references above discloses incubating the solid phase bound deaminated nucleic acid under alkaline conditions whereby the deaminated nucleic acid is desulfonated.

However, Gagna discloses that once so immobilized, the molecules can be used in various assays (See pg. [0002]). Thus, one of ordinary skill in the art would have been motivated to apply the method of Gagna for the immobilization of nucleic acid without any compound mediation and for desulfonating the solid phase bound deaminated nucleic acid under alkaline conditions. It would have been prima facie obvious for desulfonating the solid phase bound deaminated nucleic acid under alkaline conditions.

4. Claims 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herman et al. (5,786,146, issued July 28, 1998) in view of Gagna (2003/0096273, issued May 22, 2003) as applied to claims 1-5 above, and further in view of Weindel et al. (WO 01/37291, issued May 21, 2001).

The teachings of Herman et al. and Gagna are set forth in section 3 above.

Herman et al. and Gagna do not disclose the solid phase comprises magnetic glass particle, the magnetic particle has diameter between 0.5 and 5 $\mu$ m, and the magnetic glass particle is manufactured by the sol-gel method.

Weindel et al. disclose the magnetic glass particle, which can be used in nucleic acid purification (See the abstract). The magnetic glass particle is a solid dispersion of small magnetic core in glass (See pg. 4, lines 9-11). The diameter of the particle is between 5 and 500nm (See pg. 4, lines 21-23 and pg. 5, lines 13-23). The magnetic glass particle is used in nucleic acid purification from a sample containing cells. The advantage of this is its potential simplicity and high sensitivity (See pg. 17, lines 1-7). Weindel et al. also disclose the method of making the magnetic glass particle by the sol-gel method and spray-drying as recited in instant claim 11 (See

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pg. 9, lines 13-37, pg. 21 and fig. 1). The magnetic glass particle is also used in nucleic acid amplification and hybridization assay (See pg.1).

One of ordinary skill in the art would have been motivated to apply the magnetic glass particle of Weindel et al. in the method of Herman et al. as a solid support for converting cytosine bases to uracil bases because of the advantage of using the magnetic glass particle (See pg. 17, lines 1-17). It would have been prima facie obvious to apply the magnetic glass particle for the conversion of cytosine bases to uracil bases in a nucleic acid.


### **Summary**

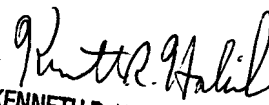
5. No claims are allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung   
November 7, 2007

  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER  
11/13/07